นิพนธ์ต้นฉบับ Original Article

The Safety and Clinical Outcome in Unprotected Intervention of Left Main Coronary Artery Stenosis in Maharat Nakhon Ratchasima Hospital

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Background: Instead of coronary artery bypass graft (CABG) for critical or severe left main artery (LMCA) disease patients, up to now percutaneous coronary intervention (PCI) with drug-eluting stent (DES) is more frequently considered in unprotected LMCA stenosis. It might be due to co-morbidities, high surgical risk, and/or patient's preference. Objective: To evaluate the safety and clinical outcome of PCI with DES (and BMS implantation) in unprotected LMCA in Maharat Nakhon Ratchasima Hospital. Patients & Methods: Retrospective review of the patients with LMCA who were treated with PCI with DES inspite of unprotected LMCA. The outcome and the immediate and late complications were i.e. major adverse cardiovascular and cerebral events (MACCE) and target vessel revascularization. The recruitment period was between October 2005 to October 2009. Results: Twenty-seven patients were enrolled, 20 of them (64%) were implanted with DES. The procedure was successful in all, but one was dead in hospital (3.7%) and two had MACCE (7.9%) in the hospital. The rest of them were followed within 6 to 48 months with repeated catheterization or 64-slides computerized tomography angiogram 19/27 (70.3%), 2 were additionally dead (7.4%), 7 developed MACCE within 6 months (25.9%) while 6 needed repeated target vessel revascularization (TVR) (22.2%). Conclusion: PCI with DES in cases of LMCA stenosis could be performed with high successful rate in spite of unprotected left main. Death rates were 3.7% and 7.4% as immediate and late complication respectively, 22.7% needed repeated TVR.

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บทคัดย่อ: ความปลอดภัยและผลทางคลินิกในการขยายหลอดเลือดหัวใจLeft Main แบบ Unprotected ในโรงพยาบาลมหาราชนครราชสีมา
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เวชสารโรงพยาบาลมหาราชนครราชสีมา 2552: 33: 161-6.

ภูมิหลัง ผู้ป่วยที่มีการตีบตันของleft main coronary artery (LMCA) ในระดับที่มีนัยสำคัญ มักจะ ใช้บการรักษาด้วย การผ่าตัดเส้นเลือดหัวใจซึ่งเ็ปเมาตรฐานในการรักษา แต่ปัจจุบันมีความกาวหน้ามากขึ้นในการรักษาโดยใส่เดลวดค้ำ ้ยันผ่านสายสวนหัวใจในผู้ป่วยส่วนหนึ่งที่ไม่สามารถผ่าตัดได้ด้วยข้อจำกัดต่อการผ่าตัด, โรคร่วมของผู้ป่วย หรือผู้ป่วย ปฏิเสธการผ่าตัดวัตถุประสงค์ เพื่อศึกษาความปลอดภัยและผลทางคลินิกในการขยานMCA แบบ unprotected ในโรง พยาบาลมหาราชนครราชสีมา**ผู้ป่วยและวิธีการ:** เป็นการศึกษากลุ่มผู้ป่วยหลอดเลือดหัวใจตีบที่ LMCA ที่ได้รับการ รักษาด้วยการใส่ขดลวดค้ำยันผ่านสายสวนหัวใจในโรงพยาบาลมหาราชนครราชสีมา ตั้งแต่ เดือนตุลาคม 2548 ถึง ้เคือนตุลาคม 2552 เพื่อดูผลการรักษาและภาวะแทรกซ้อน ได้แก่ อัตราการเสียชีวิต อัตราการเกิดกล้ามเนื้อหัวใจตาย ซ้ำ,อัตราการเกิดอัมพาตและอัตราการกลับตีบซ้ำในขณะที่อุ่ยืนโรงพยาบาลและขณะติดตามการรักษาที่6-48 เดือน ผลการศึกษา: พบผู้ป่วยหลอดเลือดหัวใจตีบที่LMCA ที่ ได้รับการรักษาโดยใส่ขดลวดค้ำยันผ่านสายสวนหัวใจในโรง พยาบาลมหาราชนครราชสีมา27 ราย ซึ่งใช้บดลวดเคลือบยา20 ใน 27 ราย (ร้อยละ 64.0) ประสบความสำเร็จ โดยไม่มี ภาวะแทรกซ้อนถึง 24 ราย (ร้อยละ 88.9), อัตราการเสียชีวิตในโรงพยาบาล 1 ใน 27 ราย (ร้อยละ 3.7), อัตราการเกิด ภาวะแทรกซ้อนทางหลอดเลือดหัวใจและหลอดเลือดสมองในโรงพยาบาล2 ใน 27 ราย (ร้อยละ 7,9) มีผู้ป่วยมาตรวจ ติดตามที่ 6 เดือนถึง 48 เดือนครบร้อยละ 100 และมีผู้ป่วยได้รับการติดตามด้วยการสวนหัวใจซ้ำหรือเอกซเรย์ คอมพิวเตอร์หลอดเลือดหัวใจชนิด 64 ภาพต่อวินาที่ 19 ใน 27 ราย (ร้อยละ 70.3) พบการเสียชีวิตเพิ่มอีก2 ราย (ร้อย ละ 7.5) และเกิดภาวะแทรกซ้อนทางหลอดเลือดหัวใจและหลอดเลือดสมองที่ 6 เคือนอีก 7 ราย (ร้อยละ 25.9) และ จำเป็นต้องขยายเส้นเลือดหัวใจซ้ำ 6 ใน 27 ราย (ร้อยละ 22.2) **สรุป:** การสวนหัวใจขยายเส้นเลือดหัวใจในตำแหน่ง left main coronary artery แบบ unprotected ในโรงพยาบาลมหาราชนครราชสีมาสามารถทำได้สำเร็จทุกราย โดยมี อัตราตายร้อยละ 3.7 ในโรงพยาบาล, อัตราตายร้อยละ 7.4 ในระยะติดตามและมีอัตราการตีบซ้ำซึ่งต้องขยายและใส่ ขดลวดซ้ำร้อยละ 22.7

Introduction

Lesions in the unprotected left main coronary artery (LMCA) disease are one of the most challenging lesion subset in percutaneous coronary intervention (PCI). The surgical revascularization is considered the standard for them⁽¹⁻⁴⁾. Some studies have demonstrated that stenting of the unprotected LMCA is feasible and appears to be a promising strategy in selected patients

especially in case of the patients' preference and refusal of coronary artery bypass graft (CABG), or co-morbid conditions resulting in high risk and the inappropriateness for emergency CABG ⁽⁵⁻¹¹⁾. Recently, use of a drugeluting stent (DES) has been associated with a low restenosis rate ⁽¹²⁻¹⁷⁾.

Patients & Methods

The patients' clinical presentation of acute coronary syndrome as stable angina, non ST elevation myocardial infarction (NSTEMI) and ST elevation myocardial infarction (STEMI) in Maharat Nakhon Ratchasima Hospital were retrospectively collected from October 2005 to October 2009, who were diagnosed significantly as LMCA disease by angiographic evidence of greater than 50% diameter stenosis. PCI was done in case of the patients' preference and refusal of CABG or high risk co-morbid conditions. Data collection was checked to confirm decease in case of loss to follow-up. Major adverse cardiovascular and cerebral events (MACCE) were followed up within 6-48 months.

Definitions

Unprotected LMCA was defined as no any previous CABG. Angiographic success was defined as a residual lesion less than 20% after angioplasty. Procedural success was defined as less than 30% residual stenosis by quantitative coronary angiogram, with no major procedure or in-hospital complications, such as death, Q-wave myocardial infarction and emergency CABG. Mid-term outcome was defined as the outcome of at least 6-month follow-up. Target vessel revascularization (TVR) was defined as repeated PCI performed within 6 to 48 months. MACCE were defined

as the outcomes of all causes of death, nonfatal myocardial infarction or target lesion revascularization during follow-up and stroke. Deaths were classified as either cardiac or noncardiac. Deaths that could not be classified, were considered as cardiac-related.

Results

Twenty-seven patients were included in this study, age range 24-91 years (mean 64.0±11.2 years). The majority were male 15/27 (55.6%). The underlying diseases comprised hypertension 14/27 (51.8%), smoking 9/27 (33.3%) and diabetes 7/27 (26.0%). We found 8/27 (29.6%) STEMI, 9/27 (33.3%) impaired left ventricular function (ejection fraction less than 40%) and 5/27 (18.5%) cardiogenic shock. (Table 1)

 Table 1 Baseline clinical characteristics of studied

 patients

	Cases (%)	
	N=27	
MaleMean	15 (55.6)	
Age-yr (range)	64.0 <u>+</u> 11.2 (24-91)	
Cardiovascular risk factor		
- Hypertension	14 (51.8)	
- Diabetes mellitus	7 (26.0)	
- Hyperlipidemia	9 (33.3)	
- Smoking	9 (33.3)	
- Family history of CAD	-	
- Obesity	-	
- Previous MI	-	
- Pervious CABG	-	
- STEMI	8 (29.6)	
- UA/NSTEMI	19 (70.3)	
- LVEF <40%	9 (33.3)	
- Congestive heart failure	10 (37.0)	
- Cardiogenic shock	5 (18.5)	

Abbreviated: CAD: coronary artery disease, MI: myocardial infarction, CABG: coronary artery bypass graft, STEMI: ST elevation myocardial infarction, UA: unstable angina, NSTEMI: non-ST elevation myocardial infarction, LVEF: left ventricular ejection fraction

Angiographically finding were 10/27 (37.0%) isolated LMCA stenosis, 5/27 (18.5%) 3-vessel disease with LMCA stenosis. Two-thirds of the patients, 20/27 (74.0%) were successfully performed PCI with DES and only 1 patient was dead on day 3 after PCI (Table 2).

Table 2 Angiographic and procedural characteristics of lesion in this study

	Cases (%)	
	N=27	
Lt main lesion location (%)		
- Ostial	11 (40.7)	
- Mid	1 (3.7)	
- Distal	13 (48.1)	
- All part	2 (7.4)	
Number of vessel disease (%)		
- Lt main disease	10 (37.0)	
- 1 vessel disease	6 (22.2)	
- 2 vessel disease	6 (22.2)	
- 3 vessel disease	5 (18.5)	
Mean diameter stenosis-mm (range)	3.6 <u>+</u> 0.28 (2.5-4.5)	
Stent diameter < 3mm	1 (3.7)	
Mean stent length-mm (range)	18.0 <u>+</u> 5.24 (8-33)	
High pressure inflation>16 ATM	7 (26.0)	
Bifurcation technique		
- Single stent (%)	23 (85.2)	
- Two stent (%)	4 (14.8)	
Find kissing (%)	13 (48.1)	
Type of stent		
- Bare metal stent	7 (26.0)	
- Drug eluting stent	20 (64.0)	
Procedural success	27 (100.0)	

Table 3 In hospital outcomes and Mid-term follow up

	Cases (%)
In hospital outcomes	
- All cause death	1 (3.7)
- MACCE	3 (11.1)
- Cardiac death	1 (3.7)
- Myocardial infarction	2 (7.4)
- Target vessel revascularization	0
Mid-term follow up 6-48 months	
- All cause death	2 (7.5)
- MACCE	7 (25.9)
- Cardiac death	0
- Target vessel revascularization	6 (23.0)

Two patients were dead, one died of refractory congestive heart failure from STEMI with cardiogenic shock and the other one died of liver cancer at 6-month follow-up. MACCE were found in 7/27 (25.9%). TVR was detected 6/27(23.0%) and 5/6 were found at Ostial left circumflex artery and 1/6 at LAD angiographically at 6-month follow-up and re-intervention with plain old fashion balloon was performed for target lesion revascularization (TLR) (Table 3). Angiography and 64-slide computer tomography follow-up schedules were

Table 4 Comparation of this study and others

Maharat	Syntax ⁽¹⁸⁾	J-cypher registry ⁽¹⁹⁾
y 7.5%	4.4%	14.4%
E 25.9%	17.6%	ND
22.7%	13.5%	Ostial-body 3.6%
		Distal Lt main
		17.1%
	y 7.5% E 25.9%	y 7.5% 4.4% E 25.9% 17.6%

Abbreviated: MACCE: major adverse cardiovascular and cerebral events, ND: no data, TLR: target lesion revascularization

arranged between 6-48 months in 20/25 (80.0%) and exercise stress test was performed in 5/25 (20.0%).

Discussion

Standard management of unprotected LMCA stenosis as a guideline is CABG. Bare metal stent (BMS) implantation was reported formerly about its long-term outcome on unprotected LMCA stenosis intervention. Recently PCI with DES showed data of reduced restenosis risk by Syntax trial and J-Cypher registry (Japanese study).

This four-year study collected data between October 2005 to October 2009 of Maharat Nakhon Ratchasima Hospital (MHR), there were 9/27 (33.0%) emergently transferred with STEMI with cardiogenic shock. They had co-morbidities and high risk for emergency CABG, or they preferred PCI. None of them had stable angina.

TLR in MHR was quite high because of high risk patients for emergency PCI. However, ostium and midshaft of LMCA PCI revealed satisfactory results without TLR.

After our retrospective analysis with good clinical outcomes, we presume that PCI of LMCA disease recommended by the American College of Cardiology/ American Heart Association (ACC/AHA) guidelines should be considered revised from Class III to be Class II a. The revolution of PCI by DES and intravascular ultrasound have been more recognized to improve on positive procedure outcomes.

Study Limitations

We had very small amount of patients to determine the efficient results because most of significant

LMCA disease were performed CABG.

Conclusions

The main findings of this study are: 1) use of DES to treat unprotected LMCA lesions appears feasible with a very high procedural success rate (100.0%), 2) a significant reduction of the occurrence of MACCE at 6-48 months is observed with acceptable results, 3) the incidence of death and cardiac death are lower despite the lack of elimination of re-stenosis and TLR, 4) all restenosis lesions in these patients are focal. Emergency percutaneous intervention of unprotected LMCA disease is feasible with fair mid-term clinical outcomes.

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